REMARKS

By the foregoing amendment, Applicant has clarified dependent claim 6 to more particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Additionally, claims 13-20 have been canceled without prejudice or disclaimer. Therefore, claims 1-12 remain pending and reconsideration of the rejections previously set forth thereto are respectfully requested in view of the following comments.

Reconsideration of the previous rejection of claims 1-12 under 35 USC §112 second paragraph, is respectfully requested.

Applicants respectfully submit that the term "substantially" is not indefinite.

The term "substantially" does not render the claims indefinite. As the Court of Appeals for the Federal Circuit has stated "the law is clear that the use of terms of degree, such as "substantially" in patent claims does not necessarily render the claims indefinite". In fact, the Court of Appeals has recognized that such "words are ubiquitous in patent claims", see *Bausch and Lomb Inc. v. Alcon Laboratories, Inc.*, 64 F2d at 240, (quoting *Andrew Corp v. Gabriel Electronics Inc.*, 847 F.2d 819, 821(Fed. Cir.), cert. denied, 488 U.S.927(1988)). Thus, the Examiner's statement that the meaning of the term "is not defined in the specification" is misplaced since, in the context of the specification, which is directed to one of ordinary skill in the art, one would know what the term "substantially" means in the context of replacing the solvent "substantially completely" with a non-solvent. With regard to claim 6, Applicants have amended the claim to more particularly point out and distinctly claimed the subject matter they regard as their invention and thus have overcome the previous rejection based on indefiniteness. Withdrawal of the rejection is therefore respectfully requested.

The previous rejection of claims 13-20 is deemed moot in view of their cancellation.

Reconsideration of the previous rejection of claims 1-12 under 35 U.S.C. §103(a) as being unpatentable over McCauley (U.S. Patent No. 5,652,365) is respectfully requested. During the international phase of the above application, the PCT Examiner raised an inventive step objection against the claims based on the prior art document EP0599376 (D2) which is of the same patent family as the cited McCauley reference.

In response to the inventive step objection raised by the PCT Examiner, Applicants filed a response to the Written Opinion (a copy of which is attached).

In such response, Applicants referred to example 3 of D2 in the response to the Written Opinion and this is identical to example 3 in the cited McCauley reference. In the international stage, the Examiner also stated that an unexpected affect (e.g. higher degree of purity) over the closest prior art (D2) could be considered as an indication of inventive step.

Herein, Applicants submit that one considering the properties of a pharmaceutical product, such as Finasteride, purity includes factors such as HPLC purity, ash content and residual solvent content.

Finasteride produced according to example 3 of D2 (and McCauley) which are identical yields a product having high chromatographic purity, but also a high residual solvent content, which is disadvantageous making the product unsuitable for pharmaceutical use. The product requires extra processing time for drying to remove the residual solvent.

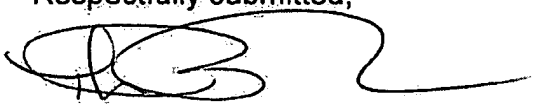
The inventors have repeated the process of example 3 of McCauley, where glacial acidic acid is used as a solvent and water is added to the solution. After isolation of the solid phase, the Finasteride is found to possess a high acetic acid content-about 5%. After 8 hours of drying, the acetic acid content was reduced to 0.5%. The prior art process precipitates Finasteride from the solvent by addition of a non-solvent, where as the claimed process crystallizes Finasteride by replacing the solvent with a non-solvent. The Finasteride product resulting from the claimed

process is essentially free of any residual solvent. The prior art does not contemplate that removal of the solvent could be affected by solvent replacement, rather than a time-consuming drying step. Thus, the present invention is unobvious over the cited McCauley reference and such would not have been obvious to an ordinary worker skilled in the art to which the invention pertains at the time of the invention.

Accordingly, withdrawal of the rejection and passage of the application to issue is respectfully requested.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1437, under Order No. 8693.015.US0000.

Respectfully submitted,



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